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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
09/976,605	10/11/2001	Grant McFadden	50082/015002	3282

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EXAMINER	
WINKLER, ULRIKE	
ART UNIT	PAPER NUMBER
1648	

DATE MAILED: 12/19/2003

Please find below and/or attached an Office communication concerning this application or proceeding.

Office Action Summary	Application No.	Applicant(s)	
	09/976,605	MCFADDEN ET AL.	
	Examiner	Art Unit	
	Ulrike Winkler	1648	

-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --

Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133).
- Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

Status

1)☒ Responsive to communication(s) filed on *October 16, 2003*.

2a)☒ This action is **FINAL**. 2b)☒ This action is non-final.

3)☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

Disposition of Claims

4)☒ Claim(s) *1-18 and 21-58* is/are pending in the application.

4a) Of the above claim(s) *1-10,14,27-31,34-46 and 48-58* is/are withdrawn from consideration.

5)☐ Claim(s) _____ is/are allowed.

6)☒ Claim(s) *11-13,15-18,22-26,32,33 and 47* is/are rejected.

7)☐ Claim(s) _____ is/are objected to.

8)☐ Claim(s) _____ are subject to restriction and/or election requirement.

Application Papers

9)☐ The specification is objected to by the Examiner.

10)☐ The drawing(s) filed on _____ is/are: a)☐ accepted or b)☐ objected to by the Examiner.

Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).

Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).

11)☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

Priority under 35 U.S.C. §§ 119 and 120

12)☐ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).

a)☐ All b)☐ Some * c)☐ None of:

1.☐ Certified copies of the priority documents have been received.

2.☐ Certified copies of the priority documents have been received in Application No. _____.

3.☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

* See the attached detailed Office action for a list of the certified copies not received.

13)☒ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. § 119(e) (to a provisional application) since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

a)☐ The translation of the foreign language provisional application has been received.

14)☐ Acknowledgment is made of a claim for domestic priority under 35 U.S.C. §§ 120 and/or 121 since a specific reference was included in the first sentence of the specification or in an Application Data Sheet. 37 CFR 1.78.

Attachment(s)

1)☒ Notice of References Cited (PTO-892)
2)☐ Notice of Draftsperson's Patent Drawing Review (PTO-948)
3)☐ Information Disclosure Statement(s) (PTO-1449) Paper No(s) _____.
4)☐ Interview Summary (PTO-413) Paper No(s). _____.
5)☐ Notice of Informal Patent Application (PTO-152)
6)☐ Other: .

DETAILED ACTION

The Amendment filed October 16, 2003 in response to the Office Action of July 17, 2003 is acknowledged and has been entered. Claims 19 and 20 are canceled. Claims 11-13, 15-18, 21-26, 32, 33 and 47 are pending and are currently being examined.

The text of those sections of Title 35, U.S. Code not included in this action can be found in a prior Office Action.

Please note that changes have been made to the amendment requirements set out in 37 CFR 1.121 (see MPEP § 714) made on June 30, 2003 (see 68 Fed. Reg. 3611, June 30, 2003). Applicant can also find this information on the USPTO website at: http://www.uspto.gov/web/offices/pac/dapp/mpepmain.html

Drawings

The drawings submitted October 16, 2003 correcting an error in the margins have been approved by the Draftsperson.

Claim Rejections - 35 USC § 112

The rejection of Claim 23 under 35 U.S.C. 112, first paragraph, as failing to comply with the written description requirement **is withdrawn** in view of applicant amendment to the claim.

The rejection of claims 11-13, 15-18 and 22-26 (note the claim amendments necessitated the addition of claims 11-13, 15 and 22-26 with the instant rejection) under 35 U.S.C. 112, first paragraph, as containing subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention **is maintained**. The specification, while being enabling for SEQ ID NO: 5, does not reasonably provide enablement for the other homologous sequences that share 99% sequence identity at the nucleotide level. The specification does not enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make the invention commensurate in scope with these claims.

Applicant's arguments have been fully considered but are not deemed persuasive. Applicant argues that it would not require undue experimentation to make the various nucleic acid changes, and that the immunomodulatory activity of a protein can be experimentally determined. Applicant argues that the effect of the expressed protein can be assayed using a chemotaxis assay. Although the claims are interpreted in light of the specification, limitations from the specification are not read into the claims. See *In re Van Geuns*, 988 F.2d 1181, 26 USPQ2d 1057 (Fed. Cir. 1993). The specification indicates that immunomodulation can encompass immunosuppression, immunostimulation, cell proliferation, apoptosis, decreasing T-cell stimulation or decreasing inflammation in an animal (see specification page 7, lines 23-25). Any protein or DNA when injected into an animal will be "immunomodulatory". Therefore, the limitation that the nucleic acid encodes an "immunomodulatory molecule" does not provide a specific measurable function using repeatable methods that can be correlated to the specific structure.

The specification discloses the identification and characterization of a *Yatapoxvirus* protein of SEQ ID NO: 4 [note in the prior office action the protein encoded by SEQ ID NO:5 was erroneously identified as SEQ ID NO:6] and the corresponding nucleic acid sequence of SEQ ID NO:5. It would be undue burden for one of skill in the art to practice the claimed invention in terms of making all the homologous sequences from the disclosed sequence, because the specification provides no guidance as to the many different homologous sequences that can be produced. A 99% homology to SEQ ID NO:5 corresponds to a change in 11 nucleotides which can result in a protein containing approximately 11 different amino acids. These nucleotide substitutions can be arranged contiguously or sparsely at different positions on a sequence. The state of the art is such that it cannot predict what substitution will result in significant structural or functional changes in the resulting protein. The classic example of structural/functional differences is hemoglobin where a single amino acid substitution due to a single nucleotide change has significant consequences on the ability of the mutant hemoglobin to carry oxygen. Another example comes from a bacterial protease (Riffkin et al. Gene Vol. 167, 1995, pp 279-283), here a change in two nucleotides of the protease sequence results in the difference between virulent and benign disease. This small difference not only results in epitope differences but also results in changes to the thermostability, elastolytic and caseinolytic activity of the protease. There is no guidance in the specification to teach where the sequence should be substituted, and therefore, the functionality of the protein would be unpredictable. Moreover, one of skill in the art would not know which position of the substitution would retain the characteristics of the polypeptide encoded by SEQ ID NO:5 without undergoing extensive

experimentation. Therefore, the instant specification does not provide enablement commensurate with the scope of the claims and the rejection is maintained.

Applicant is reminded that any amendment must point to a basis in the specification so as not to add new matter. See MPEP 714.02 and 2163.06.

Claim Rejections - 35 USC § 102

The rejection of claims 11-13, 15, 19, 20, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Neering et al. (Gene Bank Sequence, AF153912, direct submission, August 1999) **is withdrawn** in view of Applicant's amendments to the claims.

The rejection of claims 11-13, 15, 19, 20, 21, 24 and 25 are rejected under 35 U.S.C. 102(b) as being anticipated by Amano et al. (Journal of General Virology, 1995; Gene Bank Sequence, D26580; AB015885) **is withdrawn** in view of Applicant's amendments to the claims.

The rejection of claims 11 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Lee et al. (13th International Symposium of Poxvirus –Iridovirus, September 2-6, 2000.; Gene Bank Sequence, AJ293568) **is withdrawn** in view of Applicant's amendments to the claims.

The rejection of claims 11-13, 15 and 16-18 are rejected under 35 U.S.C. 102(b) as being anticipated by Paulose et al. (Micobial Pathogenisis, 1998, see IDS) **is withdrawn** in view of Applicant's amendments to the claims.

Claim Rejections - 35 USC § 103

The rejection of claims 11-13, 15, 19-22, 24-26, 32, 33 and 47 under 35 U.S.C. 103(a) as being unpatentable over Neering et al. (Gene Bank Sequence, AF153912, direct submission, August 1999) in view of Panicali et al. (U.S. Pat. No. 5,656,465) **is withdrawn** in view of Applicant's amendments to the claims.

New rejection necessitated by the amendments:

Claim 21 is objected to because of the following informalities: Claim 21 is objected to because it is dependent on a canceled claim. Appropriate correction is required.

Claims 21, 32, 33 and 47 are rejected under 35 U.S.C. 103(a) as being unpatentable over Lee et al. (Studies of Yaba-like disease virus, a yatapoxvirus, Thesis, September 25, 2000; see also Gene Bank Sequence, AJ293568) in view of Hooper et al. (U.S. Pat. No. 6,562,376).

The instant invention is drawn to a probe for analyzing Yatpoxvirus gene having a nucleic acid sequence encoding at least 6 amino acids (18 nucleotides) of SEQ ID NO:5.

Please note, in the interest of compact prosecution claim 21 has been interpreted based on the prior claim 20 (now canceled) to be an antisense sequence that can bind to a segment of DNA of SEQ ID NO:5 that would encode 6 amino acids (18 nucleotides).

Lee et al. teaches a 1444575 bp DNA sequence of a Yaba-like disease virus a Yatapoxvirus which comprises a sequence having 98% sequence identity with SEQ ID NO:5. The DNA encodes proteins predicted to be involved in immune evasion. The sequence was submitted to Gene Bank Sequence, AJ293568 (July 13, 2000). Standard sequencing techniques requires the insertion of DNA into phage, growing the phage in bacteria (in a cell) and extracting the DNA for the sequencing reaction. A DNA sequence comprises both sense and antisense strands, a poxvirus is a linear double stranded DNA virus having are coding regions on both stands hence a nucleotide segment can be both sense and antisense at the same time. The reference does not teach formulating the sequencing probes into a kit for the purpose of detecting the virus in a sample.

Hooper et al. teaches that sequences encoding a poxviral antigen are useful for diagnostic assays such a hybridization assays and polymerase chain reaction assays for the detection of poxviruses (column 6, lines 50-60).

It would have been obvious to one of ordinary skill in the art at the time the invention to utilize the primers and sequence information disclosed by Lee et al. for the purpose of detecting a poxvirus in a sample as taught by Hooper et al. One having ordinary skill in the art would have had a high expectation of success in using the primers disclosed by Lee et al. as these primers bind poxvirus DNA and were used in order to sequence the entire viral genome. It would have been obvious to one of ordinary skill in the art to package the probes into a kit for diagnostic purposes as suggested by Hooper et al. One having ordinary skill in the art would have been motivated to package the required components into a kit for the sake of conveniently providing the reagents to unskilled personnel for the purpose of diagnosing Yaba-disease like virus.

Therefore, the invention as a whole would have been *prima facie* obvious to one of ordinary skill in the art at the time the invention was made.

Allowable Subject Matter

Claims limited to the SEQ ID NO: 5 or nucleic acids which encodes SEQ ID NO 4 would be allowable.

Conclusion

No claims allowed.

Applicant's amendment necessitated the new ground(s) of rejection presented in this Office action. Accordingly, **THIS ACTION IS MADE FINAL**. See MPEP § 706.07(a). Applicant is reminded of the extension of time policy as set forth in 37 CFR 1.136(a).

A shortened statutory period for reply to this final action is set to expire THREE MONTHS from the mailing date of this action. In the event a first reply is filed within TWO MONTHS of the mailing date of this final action and the advisory action is not mailed until after the end of the THREE-MONTH shortened statutory period, then the shortened statutory period will expire on the date the advisory action is mailed, and any extension fee pursuant to 37 CFR 1.136(a) will be calculated from the mailing date of the advisory action. In no event, however, will the statutory period for reply expire later than SIX MONTHS from the date of this final action.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Ulrike Winkler, Ph.D. whose telephone number is 703-308-8294. The examiner can normally be reached M-F, 8:30 am - 5 pm.

If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, James Housel, can be reached at 703-308-4027.

The fax phone numbers for the organization where this application or proceeding is assigned are 703-308-4242 for informal communications use 703-308-4426.

Any inquiry of a general nature or relating to the status of this application or proceeding should be directed to the receptionist whose telephone number is 703-308-0196.

ULRIKE WINKLER, PH.D.
PATENT EXAMINER 12/16/03